IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF PENNSYLVANIA

BEVERLY LAMBERSON, AS ADMINISTRATRIX OF THE ESTATE OF MELINDA LAMBERSON REYNOLDS, DECEASED, *Plaintiff*	:	CIVIL ACTION NO. 09-CV-1492
v.	:	(Judge Munley)
COMMONWEALTH OF PENNSYLVANIA, *et al.*, *Defendants*	:	Electronically Filed

PLAINTIFF'S STATEMENT OF MATERIAL FACTS, PURSUANT TO LOCAL RULE 56.1, IN SUPPORT OF HER MOTION FOR PARTIAL SUMMARY JUDGMENT

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Plaintiff Beverly Lamberson, as Administratrix of the Estate of Melinda Lamberson Reynolds, Deceased, respectfully submits this Statement of material facts as to which there is no genuine issue to be tried, in support of her motion for partial summary judgment and pursuant to Local Rule 56.1. Plaintiff is also submitting herewith an Appendix ("Appendix") of supporting documents. As used herein, "plaintiff" refers to Lamberson, and "Reynolds" refers to plaintiff's decedent Melinda Lamberson Reynolds.

Opioid Drug Addiction and Methadone Maintenance Treatment

1. Reynolds was addicted to "opioid" drugs, a term which includes both "opiates," *i.e.*, drugs that are directly derived from the opium poppy, and also other drugs that – like opiates – work by binding themselves to the body's opioid receptors.

- Plaintiff's Deposition Exhibit P-1, Report of George E. Woody, M.D. (8/30/2006) ("Woody Report") at 5. (Appendix Tab F)
- Report of Robert G. Newman, M.D., M.P.H. (12/1/2011) ("Newman Report") at 1 n.1. (Appendix Tab A)

2. Addiction to opioids – whether to illicit drugs such as heroin or prescription opioids approved for use as analgesics – has been recognized for almost a century to be a chronic medical condition and not a "bad habit" that can

be eliminated given sufficient motivation. This is one of many facts as to which the parties' experts are in agreement.

- Newman Report at 3. (Appendix Tab A)
- Report of Penelope G. Ziegler, M.D. (1/5/2012) ("Ziegler Report") at 5[1] ("chronic disease of addiction") and 10 ("no cure for this disease"). (Appendix Tab B)

3. Chronic addiction to opioid drugs is a physical or mental impairment that substantially limits one or more life activities.

- Newman Report at 3 (listing "euphoria, respiratory depression and sedation" as among the "usual opioid actions"). (Appendix Tab A)

4. As both experts have explained in their reports, methadone is an opioid "agonist," *i.e.*, a drug that binds to opioid drug receptors and therefore is useful in treatment of opioid drug dependence both as a short-term medication to control withdrawal symptoms ("detoxification") and as a long-term ("maintenance") medication to assist opioid dependent patients to refrain from use of illicit drugs and to lead functional, socially productive, healthy lives.

- Newman Report at 3. (Appendix Tab A)
- Ziegler Report at 3. (Appendix Tab B)

[1] As produced by defendants, the Ziegler Report did not contain page numbers. Page numbers have been added to the copy in the Appendix for convenience of reference.

5. The experts also agree that methadone maintenance treatment is subject to exacting regulatory standards, which provide substantial assurance concerning the safety of such treatment.

- Newman Report at 12-13 ("[T]here is no other form of medical treatment – for any condition – that is subject to the same broad (and yet very detailed) range of rules, regulations and standards, and as stringent a monitoring system, as methadone maintenance.") (Appendix Tab A)

- Ziegler Report at 3 ("Methadone maintenance treatment, by definition under federal law, is provided in the context of a structured program of group and individual counseling, ongoing support and monitoring by licensed methadone clinics.") (Appendix Tab B)

6. The experts also agree that methadone maintenance treatment is extremely effective.

- Newman Report at 4-5 (citing reports by the National Institute on Drug Abuse, Institute of Medicine, National Institute of Health, Centers for Disease Control, and World Health Organization). (Appendix Tab A)

- Ziegler Report at 3-4. ("It has been shown in many studies to be the most effective and widely available treatment for heroin addiction.") (Appendix Tab B)

7. The experts also agree that a person with the disability of chronic opioid drug dependency must often continue to receive methadone maintenance treatment on a long-term or even lifelong basis.

- Newman Report at 3 ("[R]elapse to opioid use when the methadone dose is reduced or discontinued is the overwhelming rule rather than the exception. It is for this

reason that 'maintenance' treatment came to be employed on a long-term basis, and the special properties of methadone made it an ideal medication for this purpose."); *id.* at 12 ("There is neither evidence nor logic to support a time-limit on the duration of methadone maintenance treatment. Since dependence on opioids is a condition that – to date – defies cure, it is clear that regardless of duration or degree of success of treatment, the majority of individuals relapse when methadone maintenance is terminated.") (Appendix Tab A)

- Ziegler Report at 5 ("For opioid dependence, most proponents of agonist therapy recommend lifelong therapy. . . ."). (Appendix Tab B)

Melinda Lamberson Reynolds and Methadone Maintenance Treatment

8. Reynolds received methadone maintenance treatment at Morris County After-Care ("MCAC") from approximately October 1997 until February 2004. Thereafter, Reynolds received methadone maintenance treatment at New Directions Treatment Services ("New Directions" or "NDTS") in Bethlehem, Pennsylvania, from approximately March 2004 until July 2010, and from approximately September 2010 until her death in February 2012.

- MLR 017636-MLR 017770.MCAC.pdf (records of treatment, subpoenaed and produced by defendants). (Not included in Appendix)[2]

[2] Plaintiff does not believe that there is any dispute concerning the duration of Reynolds' treatment. Because of the volume of records produced from Morris County After Care, which would require redaction, these records are not included in the Appendix, but will be supplied subsequently if needed.

- MLR 017771-MLR 018745.NDTS.pdf and MLR 021019-MLR 021043 (records of treatment, subpoenaed and produced by defendants). (Not included in Appendix)[3]

Professional Licensing in Pennsylvania and Methadone Maintenance Treatment

9. Professional licensing in Pennsylvania, including licensing of nurses, is administered by defendant Pennsylvania Department of State ("DoS").

- https://www.mylicense.state.pa.us/
- Professional Nursing Law, 63 P.S. §212 *et seq.*

10. DoS receives federal financial assistance.

- PTFRFP40-000001 through 000029. (Appendix Tab G)

11. Defendant Pennsylvania Bureau of Professional and Occupational Affairs ("BPOA"), defendant Pennsylvania Division of Professional Health Monitoring Programs ("PHMP") and various licensing boards for different professions, including defendant Pennsylvania Board of Nursing ("BoN"), are part of DoS.

- http://www.dos.state.pa.us/portal/server.pt/community/bureau_of_professional___occupational_affairs/12483

[3] Plaintiff does not believe that there is any dispute concerning the duration of Reynolds' treatment. Because of the volume of records produced from New Directions, which would require redaction, these records are not included in the Appendix, but will be supplied subsequently if needed. A few specific pages from the New Directions records that are cited below for other points are included as indicated.

- 63 P.S. 212.1

12. PHMP was formerly known as the "Impaired Professionals Program." As used herein, "PHMP" includes the Impaired Professionals Program and/or the Division of Professional Health Monitoring Programs, as the context may require.

- Deposition of Pearl E. Harris (8/22/2011) at 24 (Appendix Tab C)

13. Throughout the time period when Reynolds interacted with PHMP, the Case Manager to whom she was assigned was Pearl E. Harris ("Harris"), and Harris' supervisor and the chief administrator of PHMP was Kevin Knipe ("Knipe").

- Deposition of Pearl E. Harris (8/22/2011) at 15-17, 74-75. (Appendix Tab C)
- Deposition of Kevin Knipe (8/25/2011) at 5-6. (Appendix Tab D)

14. According to a page on defendants' web-site:

> The Division of Professional Health Monitoring Programs (PHMP) of the Bureau of Professional & Occupational Affairs (BPOA) provides a method by which professionals suffering from a physical or mental impairment, such as chemical dependency, may be directed to appropriate treatment and receive monitoring to ensure that they can safely practice their licensed profession. PHMP comprises two programs, the Voluntary Recovery Program (VRP) and the Disciplinary Monitoring Unit (DMU).

- Text found on the Internet at http://www.dos.state.pa.us/portal/server.pt/community/professional_health_monitoring_programs_(phmp)/12470 on November 13, 2012

15. As stated in the text from defendants' web-site, PHMP operates both a "Voluntary Recovery Program" or "VRP" for individual licensees who are allegedly suffering from a physical or mental disability, and a "Disciplinary Monitoring Unit" or "DMU" for licensees who are subject to a consent agreement or Board Order from one of the licensing boards including the BoN.

- Deposition of Kevin Knipe (8/25/2011) at 13-15 (Appendix Tab D)

16. The same PHMP employees are responsible for both VRP cases and DMU cases.

- Deposition of Kevin Knipe (8/25/2011) at 15-16 (Appendix Tab D)

17. Since approximately 1993, PHMP has maintained a document known as "standard operating procedures" or "SOPs" which contains standards that are applied by PHMP staff members in their interactions with professional licensees who are allegedly suffering from a physical or mental disability.

- Deposition of Kevin Knipe (8/25/2011) at 11-12 (Appendix Tab D)

18. PHMP follows the SOP provisions relating to methadone both for licensees who are participating in the VRP, and licensees who are subject to the DMU.

- Deposition of Kevin Knipe (8/25/2011) at 26, 28. (Appendix Tab D)

19. According to a page on defendants' web-site, the Mission Statement of the BoN reads as follows:

> The State Board of Nursing establishes rules and regulations for the licensure and practice of professional and practical nursing in the Commonwealth of Pennsylvania and provides for the examination of all applicants. The Board examines all applicants for licensure and issues licenses for professional nursing and practical nursing to persons passing such examinations and meeting other qualifications for licensure. The Board establishes standards for the approval and operation of nursing education programs for the preparation of professional nurses (RNs) and prepares and distributes an annual list of all approved programs. In addition, the Board annually prepares and distributes a list of all Board-approved schools and institutions for the education of practical nurses (LPNs). The Board regulates certified registered nurse practitioners (CRNPs) and approves programs for their education. In addition, Act 99 of 2002 (effective 9/29/02) amended the Professional Nursing Law to include licensing of dietitian-nutritionists.
>
> - Text found on the Internet at http://www.portal.state.pa.us/portal/server.pt/community/state_board_of_nursing/12515 on November 13, 2012

The PHMP Methadone Prohibition Policy

20. From 1993 until at least June 2008, the SOPs included a section entitled "Eligibility, Licensee on Methadone Maintenance" and which is referred to herein as the "PHMP Methadone Prohibition Policy."[4] The PHMP Methadone Prohibition Policy provided in part:

[4] Minor text changes may have occurred during the time span covered by this policy, but are not material to the issues in this action.

> [A]ny licensee assessed by a PHMP-approved provider [as] in need of ongoing methadone maintenance will be declared ineligible to participate in the PHMP. **Such licensees will be referred to the Board, with the recommendation that the Board consider any individual requiring maintenance on methadone as unfit to practice**.
>
> * * * *
>
> If treatment alternatives to methadone maintenance are offered/recommended by the PHMP-approved provider, the licensee must agree to medically-supervised withdrawal from methadone within a time-frame established by the PHMP-approved provider (in consultation, whenever possible, with the methadone-administering provider) and the PHMP.

- Plaintiff's Deposition Exhibit P-2 (boldface in original). (Appendix Tab F)

21. Neither Reynolds nor anyone who was treating her for opioid drug dependency was aware of the PHMP Methadone Prohibition Policy. In fact, as late as August 30, 2010, when defendants filed their Answer to the Amended Complaint, defendants denied the existence of the policy.

- Defendants' Answer to Amended Complaint at ¶30.

22. Notwithstanding this denial, defendants. by written policy and in practice, excluded any person who was known to be receiving methadone maintenance treatment from participation in and from the benefits of their services, programs and activities relating to licensing of nurses in Pennsylvania, and from permission to work as a nurse, while the PHMP Methadone Prohibition Policy was in effect.

- Deposition of Kevin Knipe (8/25/2011) at 26-28. (Appendix Tab D)

23. Thus, PHMP and the BoN would not allow any person who was known to be receiving methadone maintenance treatment to participate in and benefit from their services, programs and activities relating to licensing of nurses in Pennsylvania, notwithstanding that both experts agree: (a) that such treatment is highly effective; (b) that many affected individuals must receive such treatment on a long-term (Dr. Newman) or even lifelong (Dr. Ziegler) basis; and (c) that at least some persons receiving methadone maintenance treatment are able to safely practice nursing.

- *See* paragraph 6, *supra*;
- *See* paragraph 7, *supra*;
- Newman Report at 7 ("tolerance to methadone makes it possible for methadone to be used as a maintenance medication to satisfy and relieve cravings for other narcotic drugs without the patient experiencing other unwanted side effects such as cognitive impairment or sedation.") (Appendix Tab A)
- Ziegler Report at 5 ("**If** cognitive deficits are found via testing, suitable accommodations may be able to be made to allow the individual to work safely in some jobs within his or her profession.") (Emphasis added.) (Appendix Tab B)

24. Defendants also concealed the existence of the PHMP Methadone Maintenance Policy during a hearing before a Hearing Examiner of defendant BoN

on July 11, 2007, during which Harris testified as follows in response to questioning by counsel for defendant DoS:

> BY MS. SHEAFFER:
>
> Q Miss Harris, you heard Miss Reynolds testify that you told her that it was Pennsylvania law that she could not work as a nurse and be on the methadone maintenance program. Did you tell her that?
>
> A I did not.
>
> Q How are you sure you did not tell her that?
>
> A There's no such law.
>
> Q To your knowledge, is there any policy or directive by the State Board of Nursing that a nurse on methadone maintenance cannot practice as a nurse?
>
> A If that is not written in the order from the Board that they cannot practice on methadone, there is nothing to my knowledge that the State Board of Nursing holds that a person cannot practice on methadone.
>
> Q Does PHMP monitor any nurses who are on methadone maintenance and who are permitted to work?
>
> A Yes.
>
> Q And there is no requirement that they cannot practice as a nurse because they're on methadone maintenance?
>
> A No.

- Plaintiff's Deposition Exhibit P-7 (Hearing Transcript 7/11/2007) at 75. (Appendix Tab F)

25. Ms. Harris knew that the PHMP Methadone Prohibition Policy was in effect at the time of the hearing.

- Plaintiff's Deposition Exhibit P-2 (Appendix Tab F)
- Deposition of Pearl E. Harris (8/22/2011) at 108-110. (Appendix Tab C)

26. Ms. Harris also knew at the time of the hearing that BoN Consent Agreements and Orders were implemented and enforced by PHMP, and that nurses who were subject to such BoN Consent Agreements and Orders were therefore subject to the PHMP Methadone Prohibition Policy, but Ms. Harris did not disclose the PHMP Methadone Prohibition Policy in her answer.

- Plaintiff's Deposition Exhibit P-2 (Appendix Tab F)
- Deposition of Pearl E. Harris (8/22/2011) at 108-110. (Appendix Tab C)

27. Ms. Harris also later acknowledged at her deposition in this case that her statement at the hearing on July 11, 2007 that PHMP was monitoring nurses "who are on methadone maintenance and who are permitted to work" was not correct "[a]t least for my caseload."

- Deposition of Pearl E. Harris (8/22/2011) at 126-127. (Appendix Tab C)

28. Just as there is a high degree of agreement between the experts concerning the efficacy of methadone maintenance treatment, there is also a high degree of agreement concerning the inappropriateness of the PHMP Methadone Prohibition Policy. Thus Dr. Newman states that this policy of "absolute prohibition" is without any "medical, scientific or empirical basis."

- Newman Report at 10. (Appendix Tab A)

29. While Dr. Ziegler's comments concerning the PHMP Methadone Prohibition Policy are couched in terms of comparison between that policy and the subsequent revised policy described below, they are nevertheless clear and forthright, and demonstrate that even defendants' expert is unable to defend the pre-June 2008 Prohibition Policy. Among other things, Dr. Ziegler states:

(a) The PHMP Methadone Prohibition Policy "failed to present a balanced picture of the overall question of treatment for opioid dependence." Ziegler Report at 10.

(b) The PHMP Methadone Prohibition Policy "did not specify involvement of a specialized addiction medicine physician/ addiction psychiatrist in decision-making about if and how to withdraw an individual from methadone who is being treated in MMT. Since such decisions can present significant medical issues, it is important that a physician be involved." *Id.*

(c) In Reynolds' individual case, the PHMP Methadone Prohibition Policy gave rise to a recommendation for "rapid detoxification," *i.e.*, rapid discontinuation of methadone therapy, which would have subjected Reynolds "to extreme and unnecessary suffering." *Id.*

- Ziegler Report at 10. (Appendix Tab B)

Evaluation of Reynolds by Dr. George E. Woody

30. George E. Woody, M.D. ("Woody") is a nationally respected addiction specialist.

- Ziegler Report at 8. (Appendix Tab B)

31. Woody was hired by defendant DoS to evaluate Reynolds, and did so on July 20, 2006.

- Plaintiff's Deposition Exhibit P-1, Woody Report (Appendix Tab F)

32. Defendant DoS received from Woody a report of his July 20, 2006 evaluation of Reynolds (the "Woody Report"). The Woody Report is dated August 30, 2006.

- Plaintiff's Deposition Exhibit P-1, Woody Report (Appendix Tab F)

33. The Woody Report stated in part:

Impression: Ms Reynolds has:

- Opioid Dependence, on methadone maintenance with evidence of excellent treatment response
- Hepatitis C with undetectable Viral load, currently in follow-up
- Generalized Anxiety Disorder – under adequate control with treatment
- Chronic insomnia

> In view·of her positive response to methadone maintenance over a period of at least 1.5 years; the absence of current unprescribed drug use by history and a review of the medical records, the psychiatric examination and urine test results that were positive only for drugs that are currently prescribed (methadone, benzodiazepine) and the report from a recent employer that her work has been good during a period of time that she has been on methadone, I think she is able to practice nursing with the requisite skill and safety provided she is monitored for a time to be determined by the Board. She expressed an interest in participating in the VRP if that is possible.
>
> This opinion is provided within a reasonable degree of medical certainty and is based on the findings that are summarized above as well as on data supporting the efficacy of methadone maintenance for treatment of opioid dependence (for a recent review see "Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs", Substance Abuse and Mental Health Administration, 2005), and could change following a review of new information.

- Plaintiff's Deposition Exhibit P-1, Woody Report at p. 5 (Appendix Tab F)

34. The recommendation in the Woody Report that Reynolds be permitted to continue on methadone maintenance treatment was in conflict with the PHMP Methadone Prohibition Policy.

- Plaintiff's Deposition Exhibit P-1, Woody Report (Appendix Tab F)
- Plaintiff's Deposition Exhibit P-2 (Appendix Tab F)

35. The PHMP Case Manager who was assigned to Reynolds' case, Pearl Harris, was aware of the existence of the Woody Report but never asked to see it.

Ms. Harris testified at her deposition in this action that she had never seen the Woody Report before it was shown to her during the deposition.

- Deposition of Pearl E. Harris (8/22/2011) at 38-41 (Appendix Tab C)

Evaluation of Reynolds by A Better Today, Inc.

36. At PHMP's direction, Reynolds was also seen on January 15, 2007 by an employee of "A Better Today, Inc." who Harris identified as "John Sery" or "John Siery" [5] (hereinafter "Siery").

- Plaintiff's Deposition Exhibit P-7 (Hearing Transcript, 7/11/2007) at 12 (Appendix Tab F)
- Plaintiff's Deposition Exhibit P-17 (date of birth redacted) (Appendix Tab F)

37. However, neither Mr. Siery nor anyone else from A Better Today, Inc. prepared a contemporaneous written report concerning Siery's evaluation.

- Plaintiff's Deposition Exhibit P-7 (Hearing Transcript, 7/11/2007) at 12 and 27-29 (Appendix Tab F)

38. Nearly six months after the A Better Today, Inc. evaluation, by which time Mr. Siery had retired, another A Better Today, Inc. employee Vincent Carolan sent a letter to Harris dated July 11, 2007 which stated in part:

[5] The name appears as "Sery" in the Hearing Transcript, but as "Fiery," and then corrected to "Siery" in a May 1, 2007 letter from Harris to Siery, Plaintiff's Deposition Exhibit P-16 (Appendix Tab F).

> Based on the physiological nature of her current ongoing dependence to Xanax[6] and Methadone, Ms. Reynolds was directed to enter into a level 3A Medical Detoxification Unit before being admitted to out-patient therapy with A Better Today.
>
> - Plaintiff's Deposition Exhibit P-17 (footnote added). (Appendix Tab F)

39. Defendants' expert in this litigation, Dr. Ziegler, reviewed the Carolan letter and provided the following comments in her report:

> Mr. Carolan's report indicates that he [sic][7] referred Melinda Reynolds to a Level 3A Medical Detoxification Unit for treatment, but that Ms. Reynolds, after agreeing to go to this program, did not in fact do so. Without more information about the details of Ms. Reynolds' condition on January 15, 2007, the dosage of methadone she was taking, and her desires regarding treatment for her opioid and benzodiazepine dependence, I cannot comment on whether this was an appropriate referral for Ms. Reynolds. However, most patients receiving MMT would not be appropriate for the type of rapid detoxification (medically managed drug withdrawal) provided in the typical Level 3A Medical Detoxification Unit. Rapidly withdrawing a patient from a maintenance dose of methadone, typically 40-100mg daily, would be extremely uncomfortable for the patient and could result in significant medical complications. Most Medical Detoxification Units insist that the patient undergo a gradual taper of methadone dosage, down to around 10mg daily, prior to entering a rapid withdrawal program. Even when this is done, the chances of the patient being able to tolerate a rapid withdrawal are not good, and many such patients leave the Detox Unit Against Medical Advise (AMA)

[6] Xanax is a trade name for the drug Alprazolam, which is part of the class of drugs known as benzodiazepines.

[7] It appears from Dr. Ziegler's report that she did not know that the evaluation was not performed by Mr. Carolan.

and either return to the methadone program or resume use of illicit opioids.

- Ziegler Report at 9 (footnote added). (Appendix Tab B)

40. Dr. Ziegler also stated elsewhere in her report, referring again to the A Better Today, Inc. letter, that "the original recommendation for rapid detoxification in an inpatient setting was not appropriate" because, among other things, "Assuming the patient was receiving a daily dosage of methadone in the 40-100mg per day range, the dosage is too high to expect to succeed in withdrawing her in 1-3 weeks without subjecting her to extreme and unnecessary suffering."

- Ziegler Report at 10. (Appendix Tab B)

41. As of January 15, 2007, the date of the A Better Today, Inc. evaluation, the methadone dose that Reynolds was then receiving at New Directions was 150 mg. per day.

- NDTS Dispensing Record at MLR 017782-017783. (Appendix Tab K)

42. William Santoro, M.D., is an addiction medicine specialist who treated Reynolds at NDTS.

- Plaintiff's Deposition Exhibit P-18. (Appendix Tab F)

43. In February 2008, Dr. Santoro contacted A Better Today, Inc. to discuss Reynolds' treatment, and to express concern about the recommendation that Reynolds be rapidly withdrawn from methadone maintenance treatment.

- Plaintiff's Deposition Exhibit P-18. (Appendix Tab F)

44. After his conversation with A Better Today, Inc., Dr. Santoro wrote a letter to Pearl Harris dated February 15, 2008, which Ms. Harris received on February 21, 2008, which described his conversation with A Better Today, Inc. as follows:

> With the patient's [Reynolds'] consent I contacted the counselor from "A Better Today" who met with her. After identifying myself as the Medical Director of a Methadone treatment facility the counselor involved in her case said, "I have nothing to say to you, this (and any patient) should never be on any medication to treat addiction . . . especially one that rips the hell out of the body." I asked him if I could quote him on that comment and he consented. He ignored my request for any scientific proof substantiating his comment; however, he told me that he did ". . . not want to get into a pissing contest with me." All this from my one and only statement that I was the Medical Director at a Methadone Clinic treating a mutual patient.
>
> The counselor went on to say that this patient, who is not using opiates, needs to be withdrawn from Methadone in a matter of days. He did concede that in doing so the patient would, in all likelihood, resume illicit opiate use. He also stated that the patient told him she was using many other drugs, which in his opinion she should stop. I went back and interviewed the patient (on this counselor's suggestion) and she told me that the only other drugs she told him she was using were prescribed medications from her personal physician. I can only conclude that the counselor believes that these medicines are also doing harm to her. The counselor made it very clear that he does not believe in the medical treatment of addiction, and possibly any other disease. He told me he was ". . . not interested in even considering any treatment for addiction developed in the past half century." I understand and respect that each person is entitled to their own opinions in medicine and that opinions are often opposing. However, if this or any other patient is to get a fair evaluation, then they should be sent to a program that is at

the very least open minded enough to consider all scientifically proven methods of treatment.

- Plaintiff's Deposition Exhibit P-18. (Appendix Tab F)

45. Dr. Ziegler's concern about the effect on Reynolds of the recommendation to rapidly discontinue methadone maintenance treatment was similar to Dr. Santoro's.

- *See* paragraphs 39 and 40, *supra*.

46. Although Ms. Harris admitted that she received Dr. Santoro's letter, she testified that she never spoke to him or wrote to him because there was "no release of information in the file for Dr. Santoro."

- Deposition of Pearl E. Harris (8/22/2011) at 114. (Appendix Tab C)

47. Harris did not make any effort to obtain a release to speak to Dr. Santoro, and the only letter that she sent to Reynolds was one that made no reference to Dr. Santoro or to Harris' need for such a Release.

- Deposition Exhibit P-19. (Appendix Tab F)
- Deposition of Pearl E. Harris (8/22/2011) at 116-120. (Appendix Tab C)

48. Even though Ms. Harris testified that she had never reviewed the Woody Report prior to her deposition in this case, PHMP and Ms. Harris were aware that Dr. Woody had evaluated Reynolds, both because the Woody Report is referred to in a BoN Order, and because Ms. Harris was present at the July 11,

2007 hearing where Dr. Woody's evaluation was discussed, including Dr. Woody's finding that Reynolds could safely practice nursing while continuing to receive methadone maintenance treatment.

- Deposition of Pearl E. Harris (8/22/2011) at 41 and 53. (Appendix Tab C)
- Plaintiff's Deposition Exhibit P-7 (Hearing Transcript, 7/11/2007), at 35-36, 68-71. (Appendix Tab F)

49. The reason that PHMP and Ms. Harris did not follow the Woody Report recommendation that Reynolds could safely practice as a nurse while receiving methadone maintenance treatment is that the Woody Report recommendation was contrary to the PHMP Methadone Prohibition Policy.

- *See* paragraphs 20 to 27, *supra*.

50. However, PHMP and Ms. Harris did not hesitate to require Reynolds to comply with the recommendations of A Better Today, Inc. for "rapid detoxification" because those recommendations were consistent with the PHMP Methadone Prohibition Policy.

- *See* paragraphs 20 to 27, *supra*.

51. The BoN Order relating to Reynolds which was entered following the July 2007 hearing before the BoN Hearing Examiner did not require Reynolds to stop receiving methadone maintenance treatment in order to return to work.

- BoN Final Order (9/18/2007) (MLR 000980 to 001013, at MLR 000998 to 001011, Hearing Examiner's Proposed Order adopted by BoN). (Appendix Tab H)

52. In March 2008, Ms. Harris, sent a letter to Reynolds which stated that her PHMP file had been "closed." Contrary to Ms. Harris' testimony at the July 11, 2007 hearing that there was no prohibition against methadone maintenance treatment "[i]f that is not written in the order from the Board," the letter also stated that a pre-condition for re-opening Reynolds' PHMP file was for A Better Today, Inc. to send PHMP a statement "indicating that you have fully and completely complied and cooperated with recommendations to enter inpatient treatment to be weaned from methadone."

- Deposition of Pearl Harris (8/22/2011) at 134. (Appendix Tab C)
- Plaintiff's Deposition Exhibit P-20. (Appendix Tab F)

53. The only stated basis for Ms. Harris' March 2008 letter stating that Reynolds' file had been "closed" was that she had not "enter[ed] inpatient treatment to be weaned from methadone."

- Plaintiff's Deposition Exhibit P-20. (Appendix Tab F)

The Revised PHMP Policy Adopted In 2008 But Never Applied To Reynolds

54. In 2008, NDTS learned that PHMP was refusing to permit Reynolds to work as a nurse because she was receiving methadone maintenance treatment.

- April 4, 2008 letter from Cooper to Basil Merenda, Commissioner, BPOA (MLR 020450). (Appendix Tab J)

55. Prior to the commencement of this litigation, defendants took the position that the written PHMP Methadone Prohibition Policy was "confidential," and therefore neither Reynolds nor Cooper nor anyone associated with NDTS had seen the written PHMP Methadone Prohibition Policy.

- Defendants' Answer to Amended Complaint at ¶30

56. Beginning in April 2008, the NDTS Executive Director Glenn Cooper ("Cooper") contacted defendants to request that defendants change the policy or practice, as applied to Reynolds, of refusing to permit licensed persons who were receiving methadone maintenance treatment to work as nurses.

- April 4, 2008 letter from Cooper to Basil Merenda, Commissioner, BPOA (MLR 020450). (Appendix Tab J)
- Plaintiff's Deposition Exhibit P-25 (April 10, 2008 letter from DoS Senior Prosecutor to Cooper). (Appendix Tab F)

57. Cooper submitted written information to defendants concerning the safety and efficacy of methadone maintenance treatment, and spoke to representatives of defendants including Knipe, and including DoS Senior Prosecuting Attorney Sheaffer.

- NDTS correspondence with DoS, MLR 020450 to MLR 020500. (Appendix Tab J)

- Plaintiff's Deposition Exhibit P-25 (April 10, 2008 letter from DoS Senior Prosecutor to Cooper). (Appendix Tab F)

- Deposition of Kevin Knipe (8/25/2011) at 38. (Appendix Tab D)

58. Cooper, along with Georgine Miller, Ph.D. who was the Clinical Supervisor at NDTS and familiar with Reynolds' case, also met with Knipe, Sheaffer and other DoS representatives in Harrisburg on May 5, 2008 to discuss Reynolds' case and methadone maintenance treatment. Other DoS representatives attending the meeting included: Peter V. Marks, Esquire (then Executive Deputy Chief Counsel of BPOA); Kerry Maloney, Esquire (a DoS Prosecuting Attorney); Joan Miller, Esquire (a DoS Prosecuting Attorney); Bernadette Paul, Esquire (a BPOA attorney); Paul Jarabeck (a DoS Prosecuting Attorney); Andy Demarest, Esquire (a DoS Prosecuting Attorney); Cliff Swift, Esquire (a DoS Prosecuting Attorney); and Jerry Smith, Esquire (DOS Office of Chief Counsel).

- Deposition Exhibit P-44 which is composed of several documents produced by defendants during the deposition of Mr. Knipe on November 9, 2011 including Notes of meeting (MLR 017393 and 017394); Memorandum (5/13/2008) from Sheaffer to Marks (MLR 017395 to 017402, partially redacted by defendants); Memorandum (6/18/2008) from Sheaffer to Marks (MLR 017403 and 017404, partially redacted by defendants). (Appendix Tab F)

- Deposition of Kevin Knipe (11/9/2011) at 131 (identification of document) and 140-141 (identification of meeting participants). (Appendix Tab E)

- NDTS Case Consultation (MLR 018580) (identification of Dr. Miller). (Appendix Tab I)

59. The Revised PHMP Policy was drafted by Knipe on or before May 28, 2008 when he appended a copy of the revised policy to a memorandum to BPOA Commissioner Basil Merenda, and BPOA Deputy Commissioner Mark Vessella.

- Deposition of Kevin Knipe (8/25/2011) at 61-64. (Appendix Tab D)
- Plaintiff's Deposition Exhibit P-27. (Appendix Tab F)

60. The Revised PHMP Policy was adopted by Knipe in June or July 2008.

- Deposition of Kevin Knipe (8/25/2008) at 25-26, 61-62. (Appendix Tab D)
- Plaintiff's Deposition Exhibit P-27. (Appendix Tab F)

61. The Revised PHMP Policy was adopted as a result of Cooper's requests for reconsideration of the Prohibition Policy in Reynolds' case.

- Plaintiff's Deposition Exhibit P-27 (5/28/2008 Memorandum from Knipe to Commissioner Merenda and Deputy Commissioner Vessella). (Appendix Tab F)
- Deposition of Kevin Knipe (8/25/2011) at 42-63. (Appendix Tab D)
- Memorandum (6/18/2008) from Sheaffer to Marks re "Telephone conference with Glen J. Cooper and Dr. Santoro on June 16, 2008), in Plaintiff's Deposition Exhibit P-44 at MLR 017403 and 017404. (Appendix Tab F)

62. Knipe, Marks, and Sheaffer participated in a telephone conference call with Cooper and Dr. Santoro on June 16, 2008 in which they told Cooper and Santoro that they would be revising the Methadone Prohibition Policy but that "the details have not been worked out yet," and that they would take his request for a copy "under advisement."

- Memorandum (6/18/2008) from Sheaffer to Marks re "Telephone conference with Glen J. Cooper and Dr. Santoro on June 16, 2008), in Plaintiff's Deposition Exhibit P-44 at MLR 017403 and 017404. (Appendix Tab F)

63. In fact, however, the details of the Revised PHMP Policy had already been "worked out" before this telephone conference, because the revised policy was contained in Knipe's May 28, 2008 Memorandum to Commissioner Merenda and Deputy Commissioner Vessella.

- *See* paragraph 59, *supra*.

64. The Revised PHMP Policy covered "maintenance medications for . . . [treatment of] addiction" including both methadone and buprenorphine.

- Plaintiff's Deposition Exhibit P-3. (Appendix Tab F)
- Plaintiff's Deposition Exhibit P-27 at pp. 5-6. (Appendix Tab F)

65. Buprenorphine is the chemical name for a different drug which is a partial agonist, sold under various trade-names including Suboxone® and Subutex®, and is an alternative to methadone for treatment of chronic opioid drug

dependence. Reynolds was not treated with buprenorphine.[8] In the Revised PHMP Policy, licensed individuals receiving maintenance treatment with either methadone or buprenorphine are treated alike.

- Ziegler Report at 3. (Appendix Tab B)
- Plaintiff's Deposition Exhibit P-3. (Appendix Tab F)
- Plaintiff's Deposition Exhibit P-27 at pp. 5-6. (Appendix Tab F)

66. Under the Revised PHMP Policy as written, a person receiving methadone maintenance treatment (or maintenance treatment with buprenorphine) could return to work if, but only if she obtained testing (at her expense) by a neuropsychologist approved by PHMP who confirmed that she did not "exhibit any cognitive deficits which may affect [her] ability to practice the profession."

- Plaintiff's Deposition Exhibit P-3. (Appendix Tab F)
- Plaintiff's Deposition Exhibit P-27 at pp. 5-6. (Appendix Tab F)

67. The Revised PHMP Policy does not require "neuropsychological testing" for persons with chronic opioid drug dependency who are not currently receiving maintenance treatment.

[8] Although not directly relevant to this case, Mr. Knipe testified that under the Methadone Prohibition Policy that was in effect prior to June 2008, a licensed person receiving buprenorphine would not have been permitted to work as a nurse. Deposition of Kevin Knipe (8/25/2011) at 37. (Appendix Tab D)

- Deposition of Kevin Knipe (8/25/2011) at 24-25. (Appendix Tab D)

68. Even though the Revised PHMP Policy was adopted as a direct result of Cooper's efforts on behalf of Reynolds, defendants refused to apply the Revised PHMP Policy to Reynolds.

- Plaintiff's Deposition Exhibit P-44 at MLR 017404. (Appendix Tab F)

69. Despite Cooper's requests, defendants never informed Reynolds or New Directions or Cooper or Santoro that they had adopted the Revised PHMP Policy. In fact, defendants admitted in their Answer to the Amended Complaint that "representatives from NDTS have verbally requested copies of PHMP's operating procedures for the eligibility of licensees on methadone maintenance. These requests were denied based on confidentiality."

- Deposition of Kevin Knipe (8/25/2011) at 63-64. (Appendix Tab D)
- Defendants' Answer to Amended Complaint at ¶30.

70. Although the parties' experts disagree concerning the requirement of the PHMP Revised Policy for neuropsychological testing to confirm the absence of cognitive deficits,[9] and plaintiff contends that this requirement constitutes discrimination in violation of the Americans With Disabilities Act and the

[9] *Compare* Newman Report (Appendix Tab A) at 10-11 *with* Ziegler Report (Appendix Tab B) at 5.

Rehabilitation Act, it is undisputed that Dr. Woody stated in his report, which predates the PHMP Revised Policy by several years, that Reynolds exhibited "no obvious signs of cognitive impairment:

> Her mood was neither elated· nor depressed and her affect was appropriate and moved through a normal range. Her associations were logical and goal-directed, and she easily followed the train of conversation. There was no evidence of delusions, hallucinations, paranoia, homicidal, or suicidal ideation. Her thought content focused on her wish to be able to continue working as a nurse. . . . Insight and judgment were intact as she readily acknowledged the need of the State to evaluate her.
>
> Her memory for recent and past events was good and she readily followed the train of conversation with no obvious signs of cognitive impairment. . . .

- Plaintiff's Deposition Exhibit 1, Woody Report at p. 4. (Appendix Tab F)

71. Any uncertainty about Reynolds' ability to comply with the PHMP Revised Policy, at the time that it was revised in or about June or July 2008, is the result of defendants' failure to notify Reynolds of the availability and requirements of the new policy.

- *See* paragraph 69, *supra*.

Respectfully submitted,

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